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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/822,698	HOOGENBOOM ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *30-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the invention of the different groups share the same technical features. This is not found persuasive because the inventions of the different groups are distinct and independent. Applicant is entitled to one invention per patent. U.S. restriction practice allows for the examiner to separate or restrict inventions when the claims represent inventions that are independent and distinct from one another and when the inventions would pose undue burden onto the examiner for searching. If the inventions fit these criteria, then restriction is proper. In the instant case, the inventions are distinct in that they are classified in different classes and subclasses. Furthermore, the products differ one from the other in that they have different chemical structures and functions, and the methods are used for different purposes and have different outcomes. The search for the different products and methods do not require a search within the same databases, and a search for all the different groups would force the examiner to cross reference multiple databases to determine if the instant invention was indeed novel. Therefore, the search is non-coextensive and does not over lap, thereby posing undue burden onto the examiner for searching.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-69 are pending and claims 30-69 are withdrawn from consideration as being drawn to a non-elected subject matter. Applicant is reminded to cancel all non-pending claims.

3. Claims 1-29 are therefore examined on the record.

Information Disclosure Statement

4. The Information Disclosure Statement filed 10/16/2001 (paper no. 7) is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. Claims 3-14, 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 3 and dependent claims thereof in the recitation of the phrase "portion thereof", it is unclear as to which portion of the sequence the applicant intends to include within the scope of the claim. As such the metes and bounds of the claims cannot be determined.

7. Regarding claims 4 and dependent claims thereof in the recitation of the terms "substitutions" and "combinations", it is unclear as to which substitutions or combinations the applicant is referring. There are numerous possible substitution or combinations that are possible and because the claims do not specifically limit the types or actual substitution or combination, the metes and bounds of the terms cannot be adequately determined.

8. Regarding claims 18-29 in the recitation of the term "about" it is a relative term that the specification has not adequately defined. It is unclear as to how much deviation from the percentages represented in claims 18-29 the actual numbers represent. As such the metes and bounds of the term cannot be determined.

Claim Rejections - 35 USC § 112, 1st paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description for this case has only set forth MUC1-specific binding members defined by specific sequence identification numbers and therefore the written description is not commensurate in scope to claims that read on antigen binding members of having the formula represented by portions of sequences, substitutions of sequences, combinations of sequences, sequences that are 70%, 80%, 90%, 95%, 97%, and 99% homologous.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of the sequences defined in the specification, the skilled artisan cannot envision the detailed structure of the encompassed sequences represented by portions of sequences, substitutions of sequences, combinations of sequences, sequences that are 70%, 80%, 90%, 95%, 97%, and 99% homologous and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The amino acid sequence itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Although these court findings are drawn to DNA art, the findings are clearly applicable to the claimed proteins.

Furthermore, although specifically drawn to the DNA art the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus

is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of portions of sequences, substitutions of sequences, combinations of sequences, sequences that are 70%, 80%, 90%, 95%, 97%, and 99% homologous is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated MUC1-specific binding member defined by the sequence identification umbers present in the specification meets the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112, 1st paragraph

11. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 15-17 recite specific cell lines.

It is apparent that the recited cell lines are required to practice the claimed invention, because they are specifically required in the claims. As required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is

not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the cell lines listed in claim 7. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the cell lines of claim 15-17, and they do not appear to be readily available material. Deposit of the cell lines would satisfy the enablement requirements of 35 U.S.C. 112. While the specification states on page 5 that the cell lines "have been deposited for patent purposes", the specification does not indicate the terms of the deposit.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 4-8, 18-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Arathoon R *et al* (WO 98/50431; 12 Nov 1998). Claims are drawn to a MUC-1 specific binding member wherein the antigen binding domain comprises a CDR comprising an amino acid sequence selected from a group of which includes amino acids 50-66 of

SEQ ID No: 3. The claims are further limited to a MUC1 binding member that is part of a fusion protein, is conjugated to a detectable label, more specifically an epitope tag and is a scFv or a diabody. In addition, the claims are drawn to a binding member that is about 70-99% homologous to any of the amino acids taught in claims 1-4. Arathoon R *et al* teach a multispecific antibody that comprises amino acids 50-66 of SEQ ID No: 3 and further disclose the making of a single chain Fv and or a multispecific antibody that comprises this sequence. Arathoon *et al* also teach of fusing the antibody to a epitope tag thereby making a fusion protein. Because the amino acid sequence taught by Arathoon R *et al* is identical to amino acids 50-66 of SEQ ID No: 3, it reads on sequences that are 70-99% homologous to any one of the sequences taught in claims 1-4, specifically amino acids 50-66 of SEQ ID No: 3.

Claim Rejections - 35 USC § 102

14. Claims 4,8, and 18-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanappik A *et al* (WO 97/08320; 6 March 1997). Claims are drawn to a MUC-1 specific binding member wherein the antigen binding domain comprises a CDR comprising an amino acid sequence selected from a group of which includes amino acids 50-66 of SEQ ID No: 3. The claims are further limited to a MUC1 binding member that is part of a fusion protein, is conjugated to a detectable label, more specifically an epitope tag and is a scFv or a diabody. In addition, the claims are drawn to a binding member that is about 70-99% homologous to any of the amino acids taught in claims 1-4. Kanappik A *et al* teach an amino acid sequence that is identical to that of amino acids 31-35 of SEQ ID No: 3 and further teach of using the amino acid sequences as

part of a single chain Fv antibody, and Fab fragments. Because the amino acid sequence taught by Kanappik A *et al* is identical to amino acids 31-35 of SEQ ID No: 3, it reads on sequences that are 70-99% homologous to any of the one of the sequences taught in claims 1-4, specifically amino acids 31-35 of SEQ ID No: 3

Claim Rejections - 35 USC § 102

15. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Brugger *et al* (J Clin Oncol 1999 May;17(5):1535-44). Claims 1 and 2 are drawn to an isolated MUC-1 binding member comprising an antigen binding domain. Brugger *et al* disclose an antibody that is able to bind to the MUC-1 protein. Since it cannot be determined from the recited claims what the actual sequence claimed is, the claims read on any antibody capable of binding to the MUC-1 antigen. Since the USPTO does not have the facilities to prove otherwise and because the formula presented does not specifically claim the instant antigen binding member, in the absence of evidence to the contrary, the antibody taught by Brugger *et al* is the same as that taught in the instant invention.

Conclusion

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone

numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
March 24, 2003

ALI R. SALIMI
PRIMARY EXAMINER